

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
DANVILLE DIVISION**

The United States of America, ex rel. Joseph
M. Thomas,

Plaintiff,

v.

Civil Action No. 4:13-CV-00017

Duke University, Duke University Health
System, Inc., William M. Foster, Ph.D., and
Erin N. Potts-Kant,

ORAL ARGUMENT REQUESTED

Defendants.

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS
DUKE UNIVERSITY AND DUKE UNIVERSITY HEALTH SYSTEM, INC.
MOTION TO DISMISS RELATOR'S AMENDED COMPLAINT WITH PREJUDICE**

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Defendants Duke University (“Duke”) and Duke University Health System (“DUHS”) (collectively, the “Defendants”) hereby bring this Motion to Dismiss Relator’s Amended Complaint with prejudice pursuant to Federal Rules of Civil Procedure 8(a), 9(b), and 12(b)(6). In support of its Motion, Defendants state as follows:

I. INTRODUCTION

Relator’s Amended Complaint fails to meet the pleading requirements of Federal Rules of Civil Procedure 8(a), 12(b)(6) and 9(b). In spite of his broad allegations of improper laboratory research practices, Relator has failed to plead the elements of a False Claims Act (“FCA”) action, which is required to survive a Rule 12(b)(6) motion to dismiss. First, Relator has failed to identify plausible facts that *any actual, false claim* was submitted by Defendants to the government – the *sine qua non* of an FCA violation. Second, Relator has failed to plead that data included in actual grant applications or progress reports submitted to the government were false. Third, Relator has failed to plead materiality pursuant to the standards required by the Supreme Court in *Univ. Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). Fourth, Relator has failed to allege that any of Defendants had knowledge that allegedly false data were included in grant applications or progress reports. As a result, Relator’s Amended Complaint fails to meet the standards required by Rule 12(b)(6).

Moreover, Relator’s Amended Complaint fails to meet the heightened pleading requirements of Rule 9(b), which is required in an FCA action. Under well-settled Fourth Circuit case law, Relator was required to identify the specifics of representative, false claims, including the dates claims were submitted, what payments were requested from and made by the government, what was false about the claims, and other reliable indicia that would allow the Court to infer that some specific, false claim was submitted to a government agency. In addition, Relator has failed to provide the requisite details of falsity. Relator’s failure to identify even a

single false claim submitted to the government requires dismissal of FCA allegations pursuant to Rule 9(b). *United States ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 456-58 (4th Cir. 2013).

Lastly, all of Relator's claims against Defendant DUHS must be dismissed because (1) Counts I through IV in Relator's Amended Complaint fail to specifically mention any factual allegations concerning DUHS at all; and (2) even where Relator specifically names DUHS in Count V, his allegations fail to differentiate between DUHS's conduct and Duke's conduct. *See* Dkt. 25, ¶ 394. *See United States ex rel. Ahumada v. Nat'l. Ctr. for Emp't of the Disabled*, No. 1:06-CV-713, 2013 WL 2322836, at *3-4 (E.D. Va. May 22, 2013), *aff'd*, *United States ex rel. Ahumada v. NISH*, 756 F.3d 268 (4th Cir. 2014) (dismissing a complaint against one of the defendants where the relator failed to plead any of the particulars required by Rule 9(b) against that specific defendant).

II. BACKGROUND

A. Facts¹

Duke is a private non-profit university located in Durham, North Carolina. *See* Dkt. 25, ¶ 19. DUHS is a healthcare services non-profit corporation also principally located in Durham, North Carolina. *Id.* ¶ 20. Multiple academic departments at Duke, including the Department of Medicine, receive funding from governmental agencies and non-governmental sources for scientific research. Relator has not alleged that DUHS received funding from any of the grants that Relator has alleged are at issue in this matter. *See* Dkt. 25, Ex. C & ¶ 366 (federal funds

¹ For purposes of Defendants' motion, we presume all well-pleaded facts alleged by Relator in his Amended Complaint are true as required by applicable case law. The recitation of any allegation from the Amended Complaint should not be interpreted as an admission that the allegation is wholly or partially true. Defendants have not yet filed an Answer to the Amended Complaint and fully reserve all rights to admit or deny any allegation contained therein.

paid “*to Duke University*”) (emphasis added); Ex. C-1 (grants paid “*to Other Institutions*” do not include DUHS) (emphasis added).

The Pulmonary, Allergy, and Critical Care Medicine Division of Duke’s Department of Medicine (the “Pulmonary Division”) conducts animal research regarding all aspects of lung physiology. *Id.* ¶ 29. Dr. William M. Foster, Ph.D., was employed as a Research Professor of Medicine in the Pulmonary Division at Duke during the time period alleged in Relator’s Amended Complaint. *Id.* ¶ 24. As a Research Professor, Dr. Foster was a Principal Investigator (“PI”) in the Inhalation and Toxicology Core Laboratory, which conducted research regarding airway inflammation in mice. *Id.* ¶¶ 26; 31. Erin Potts-Kant (“Potts-Kant”) worked as a research technician within the Inhalation and Toxicology Core Laboratory in the Pulmonary Division at Duke from 2005 through March 2013. *Id.* ¶¶ 22; 229. As a research technician, Potts-Kant ran the *flexiVent* machine, which assesses lung physiology in mice. *Id.* ¶¶ 147-48. She also performed experiments on the Bio-Plex machine, which was used to analyze samples of biological materials from mice. *Id.* ¶¶ 147; 149.

Relator Joseph Thomas (“Relator”) was employed as a research technician within the Cell Biology Division of the Department of Medicine from August 2008 to February 2012. *Id.* ¶ 17. In February 2012, Relator joined the Pulmonary Division in Dr. Monica Kraft’s laboratory, where he “developed, designed, and conducted experiments for the Pulmonary Division.” *Id.* ¶ 18.

In early 2013, Duke discovered that Potts-Kant had embezzled grant funds from Duke by submitting fabricated invoices for supplies allegedly used in research experiments. *Id.* ¶¶ 227-28. Upon discovery of the embezzlement, Duke terminated Potts-Kant’s employment in March

2013. *Id.* ¶ 229.² Multiple research scientists/PIs undertook a review of *flexiVent* and Bio-Plex data that Potts-Kant had produced during her employment at Duke. *Id.* ¶ 230. This process involved reanalyzing raw data produced by the machines themselves and repeating experiments. *Id.* Many of the researchers or PIs and other individuals – *including the Relator himself* – participated in this review process to determine whether Potts-Kant had falsified or fabricated data during her employment. *Id.* ¶ 232.

B. Procedural History

On May 17, 2013, shortly after the discovery of Potts-Kant’s embezzlement and her termination, Relator commenced the case at hand by filing a sealed complaint with the Court pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. §§ 3729-3733. *See* Dkt. 1 (“Original Complaint”). Relator filed an amended complaint on November 13, 2015. *See* Dkt. 25 (“Amended Complaint”). After more than three years of investigating, the Government declined to intervene on August 8, 2016, and the Court unsealed this case on August 9, 2016.³ *See* Dkt. 35; 36.

C. Relator’s Allegations

Relator’s Amended Complaint alleges that both Duke and DUHS violated the FCA in the following ways: (1) presentment of a false claim under 3729(a)(1)(A) (the “false claim” provision), *see* Dkt. 25, Counts I and IV; (2) making or using a false record or statement that is material to a false claim being paid under § 3729(a)(1)(B) (the “false record” provision), *see id.*

² Upon information and belief, Potts-Kant pleaded guilty to two counts of common law forgery and agreed to pay restitution of \$17,500 to Duke University.

³ Defendants filed a Motion to Transfer Venue to the Middle District of North Carolina on January 4, 2017. *See* Dkt. 68, 69. Defendants respectfully request that the Court rule on its Motion to Transfer Venue prior to its Motion to Dismiss.

Counts II and V; and (3) concealing or improperly attempting to avoid or decrease an obligation to repay money under § 3729(a)(1)(G) (the “reverse false claim” provision), *see id.* Count III.

The primary theory underlying Relator’s claims in Counts I, II, and III appears to be that between 2006 and 2014:⁴ (1) one research technician, Potts-Kant, falsified or fabricated research data during various points of her employment at Duke or DUHS; *see id.* ¶¶ 5; 22-23; 154-157; (2) the falsified or fabricated research data were used in scholarly articles that referenced having received financial support from certain federally funded grants,⁵ *see id.* ¶¶ 159-160; 214-223; (3) because scholarly publications that result from government-funded research must be identified in progress reports to the granting agencies, the same published false or fabricated data ***must also have been included*** in any grant application or progress report claim for payment submitted to federal agencies, *see id.* ¶¶ 159-160; 216; 218-219; and (4) therefore, at least according to Relator, Defendants ***must have*** submitted false claims to the government.

The primary theory underlying Counts IV and V in Relator’s Amended Complaint is that Defendants made express or implied false certifications to the government by: (1) certifying compliance with the terms and conditions of grant awards in connection with grants referenced in Exhibit C that were false based on the alleged inclusion of Potts-Kant’s false data in grant submissions, *see id.* ¶ 224; (2) failing to “foster a research environment that discourages research misconduct” and failing “to deal forthrightly with possible research misconduct,” as required by law, *see id.* ¶ 225; (3) certifying compliance with certain requirements in Duke’s Institutional

⁴ Despite Relator’s factual allegations generally being limited to 2006 through 2014, in Counts IV and V of the Amended Complaint, Relator alleges that Defendants made false certifications to the government on claims for payment between 2007 and 2015. *See* Dkt. 25, ¶¶ 382, 395. Relator’s inconsistency in even identifying the time period in this matter is further evidence that he has not been able to adequately plead what is at issue in this FCA action.

⁵ For example, Relator alleges that “[t]his scientific paper, premised upon fraudulent research, cites financial support from NIH grants ES016126, ES020426, ES016347 and HL081825.” *See* Dkt. 25, ¶ 170.

Assurance and Annual Reports that Defendants failed to meet; *see id.* ¶ 226; and (4) therefore, violating the terms and conditions of their federal grants.

All of the allegations in Counts I through V are premised on Relator's pure speculation that materially false data produced by Potts-Kant and subsequently included in scientific journal articles *must have* also been submitted in claims for payment to grant agencies pursuant to certain rules and regulations governing federal grant funding. This attempt to plead fraud through regulatory interpretation is entirely speculative and fails to meet the plausibility standard of Rule 12(b)(6), much less the particularity requirement of Rule 9(b). As a result and for the additional reasons set forth below, Defendants respectfully request that the Court dismiss Relator's Amended Complaint in its entirety with prejudice because further amendment would be futile.

III. LEGAL STANDARD

A. The False Claims Act

As discussed above, Relator's Amended Complaint asserts FCA claims under 31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B), and (a)(1)(G). *See* Dkt. 25, ¶¶ 346-402. To adequately plead a violation of § 3729(a)(1)(A) of the FCA, a relator must allege that: (1) a claim for payment was submitted to the United States; (2) the claim was false or fraudulent; (3) the person acted knowing that the claim was false or fraudulent; and (4) the false or fraudulent claim was material. *See* 31 U.S.C. § 3729(a)(1)(A). To allege a violation of § 3729(a)(1)(B), in addition to the § 3729(a)(1)(A) elements, a relator must also allege that a person made (or caused to be made) a false record or statement used in support of a false claim. *Id.* To plead "reverse false claims" under § 3729(a)(1)(G), a relator must plead with particularity that the defendants "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or

knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” *Id.* Thus, the reverse false claims provision requires a relator to identify *payment received from the government* as the result of the submission of false *claims* to which the recipient was not entitled. *See id.*

B. Rule 12(b)(6) – A Complaint Must Contain Factual Allegations Supporting a Claim That Is Plausible on its Face.

A motion to dismiss a complaint under Rule 12(b)(6) should be granted unless the complaint alleges “enough facts to state a claim to relief that is plausible on its face” under Rule 8(a). *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Walters v. McMahan*, 684 F.3d 435, 439 (4th Cir. 2012). This standard “requires a plaintiff to demonstrate more than ‘a sheer possibility that a defendant has acted unlawfully.’” *Francis v. Giacomelli*, 588 F.3d 186, 193 (4th Cir. 2009) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)), and necessitates the pleading of “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Robertson v. Sea Pines Real Estate Co., Inc.*, 679 F.3d 278, 287 (4th Cir. 2012) (internal quotations omitted). “A pleading that offers labels and conclusions[,] or a formulaic recitation of the elements of a cause of action . . . [or] naked assertions devoid of further factual enhancement” will not survive a motion to dismiss pursuant to Rule 12(b)(6). *Iqbal*, 556 U.S. at 678 (internal quotations omitted); *see also Nathan*, 707 F.3d at 455 (providing that “[f]acts that are ‘merely consistent with’ liability do not establish a plausible claim to relief”) (citation omitted).

Although a court must accept as true all of the allegations in a complaint, that tenet is inapplicable to legal conclusions, and “[t]hreadbare recitals of the elements of a cause of action[.]” *Iqbal*, at 678; *see also Wag More Dogs, LLC v. Cozart*, 680 F.3d 359, 365 (4th Cir. 2012) (finding that although the Court is required to review “the facts in the light most favorable

to the plaintiff” on a motion to dismiss, it “need not accept legal conclusions couched as facts or unwarranted inferences, unreasonable conclusions, or argument”) (internal quotations omitted); *Aziz v. Alcolac, Inc.*, 658 F.3d 388, 391 (4th Cir. 2011) (providing that “statements of bare legal conclusions are not entitled to the assumption of truth and are insufficient to state a claim”) (internal quotations omitted).

C. Rule 9(b) – Fraud Must be Pleaded with Particularity.

In addition to meeting the Rule 12(b)(6) plausibility standard, because FCA actions are based in fraud, the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) also apply. *See Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999). Rule 9(b) requires that a complaint “state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). The purpose of this heightened pleading standard is to provide a defendant with notice of its alleged misconduct, prevent frivolous lawsuits or suits where facts are learned only during discovery, and protect the reputations of defendants from harm. *Nathan*, 707 F.3d at 456. In the context of the FCA, the Fourth Circuit has stated that Rule 9(b) applies with “particular force . . . given the potential consequences flowing from allegations of fraud by companies who transact business with the government.” *Id.* Failure to comply with Rule 9(b) is treated as a failure to state a claim under Rule 12(b)(6). *See United States ex rel. Jones v. Collegiate Funding Servs., Inc.*, 469 F. App’x 244, 257 (4th Cir. 2012).

To satisfy the pleading requirements of Rule 9(b), an FCA plaintiff “must, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.” *Nathan*, 707 F.3d at 455-56 (quoting *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008)). This pleading standard typically requires the relator to plead the “who, what, when,

where, and how of the alleged fraud.” *Kellogg Brown & Root*, 525 F.3d at 379 (internal quotations omitted); *see also Virginia ex rel. Hunter Labs., LLC v. Quest Diagnostics, Inc.*, No. 1:13-CV-1129, 2014 WL 1928211, at *7 (E.D. Va. May 13, 2014).⁶

Most importantly, it is not enough under Rule 9(b) for a relator to “describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments *must have* been submitted, *were likely* submitted or *should have* been submitted to the Government.” *Nathan*, 707 F.3d at 456-57 (emphasis added) (quoting *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1313 (11th Cir. 2002)). While Rule 9(b) does not require a relator to identify all false claims, it does require the relator to identify “some representative claims.” *Hunter Labs.*, 2014 WL 1928211, at *7. Without the identification of such representative claims, a relator’s FCA complaint must be dismissed. *See id.* at *8 (dismissing complaint because relator did not plead the specifics of even a single false claim).

IV. ARGUMENT

Relator’s Amended Complaint is fatally flawed as it fails to allege plausible and particularized facts required by Federal Rules of Civil Procedure 8(a), 9(b), and 12(b)(6). First, Relator has failed to plead the essential elements of an FCA action required by Rule 12(b)(6): (1) a claim for payment; (2) falsity; (3) materiality; and (4) knowledge. Second, Relator has not alleged the “who, what, where, when, and how” particulars regarding false claims submitted to the government as required by Rule 9(b). Last, Relator has not pleaded any facts regarding false claims that DUHS submitted to the government. As a result, and for the reasons set forth below,

⁶ Although the relator in *Hunter Labs* brought claims pursuant to the Virginia Fraud Against Taxpayers Act (“VFATA”) and not the federal FCA, the “similarity of the language of the [VFATA and FCA] makes it clear that the Virginia General Assembly intended to pattern the VFATA after the FCA[.]” and the same analysis applies to both statutes. *See United States ex rel. Johnson v. Univ. Health Servs., Inc.*, 889 F. Supp. 2d 791, 793 (W.D. Va. 2012).

Defendants respectfully request that this Court grant its Motion to Dismiss Relator's Amended Complaint in its entirety with prejudice pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b).

A. The Amended Complaint Does Not State a Cause of Action Under FCA Sections 3729(a)(1)(A), 3729(a)(1)(B), or 3729(a)(1)(G) and Must Be Dismissed Under Rule 12(b)(6).

As stated in Section II.C *supra*, Counts I and IV of the Amended Complaint allege that Defendants violated 31 U.S.C. § 3729(a)(1)(A) (the “false claim” provision) by knowingly presenting, or causing to be presented, a false or fraudulent *claim* for payment to the government. *See* Dkt. 25 ¶¶ 346-359; 380-391. Similarly, Counts II and V of the Amended Complaint allege that Defendants violated § 3729(a)(1)(B) (the “false record” provision) by knowingly presenting, or causing to be presented, a false or fraudulent *record or statement* in order to get a false *claim* paid by the government. (*See* Dkt. 25 ¶¶ 360-369; 392-402). Count III of the Amended Complaint alleges that Defendants violated § 3729(a)(1)(G) (the “reverse false claim” provision) by knowingly making or using a false record or statement material to Duke University's obligation to repay grant funds and knowingly concealing or knowingly and improperly attempting to avoid or decrease Duke University's obligation to repay grant funds.

As discussed below, the Amended Complaint fails to state a cause of action under any FCA theory of liability because Relator has not plead that (1) even one false claim or certification was presented to the government for payment; (2) any such claim or certification was false or fraudulent; (3) any allegedly false data or certifications were material; (4) Defendants acted with the requisite scienter; and (5) Defendants made a false certification under the standards embraced by the Supreme Court in *Escobar*. As a result, Relator's Amended Complaint should be dismissed for failing to state a claim upon which relief may be granted under Rule 12(b)(6).

1. The Amended Complaint Does Not Plead Plausible Facts Showing that Defendants Made a Claim Seeking Payment from the Government and Must Be Dismissed Under Rule 12(b)(6).

Liability under the FCA often arises from the submission of false claims to the government. § 3729(a)(1)(A)-(B). Because the presentment of an *actual* false claim is the *sine qua non* of an FCA action, Relator must allege enough plausible facts to show that Defendants actually submitted a false claim for payment to the government. *See Nathan*, 707 F.3d at 456-57; *Twombly*, 550 U.S. at 570; *Walters*, 684 F.3d at 439. Relator's Amended Complaint is fatally flawed as it does not plead such plausible facts.

According to Relator, Defendants “engaged in systemic research misconduct and fraud . . . failed to comply with the terms, conditions and assurance of their grant awards . . . used false and/or fabricated research results to obtain millions of dollars of medical research grants from the NIH, the EPA and other federal agencies, and . . . used grants funds to generate false and/or fabricated research results.” Dkt. 25 ¶ 3. However, Relator never alleges that Defendants submitted even one actual false claim for payment (*e.g.*, a grant application or progress report) for payment. Rather, Relator lists a number of *articles* that appeared in scientific journals and alleges those articles were impacted by the alleged research misconduct. *See id.* ¶¶ 162-212; *see also* Ex. E. Realizing that these publications were not themselves claims for payment to any government agency, Relator attempts to link the allegedly false data included in these publications to claims for payment made in grant applications or progress reports by citing to various grant instructions which, according to Relator, required Defendants to include the *same data* from the publications in grant applications or progress reports if the publication reported that the authors had received financial support from that grant. *See, e.g., id.* ¶¶ 217-19. Specifically, Relator alleges that:

The interaction among grant applications, grant progress reports, and publications establish that Duke University made the same false reports of research results to the NIH and the EPA as were made in the publications funded by NIH and EPA grants. The sequence and required content of grant progress reports required that Duke University report its claimed research results each year and identify to the NIH and the EPA the publications that were funded by the grants. The false research results reported in Potts-Kant's and Foster's publications, therefore, *in many cases*, were also reported to the NIH and the EPA in Duke University's grant progress reports.

Dkt. 25 ¶ 218 (emphasis added) *see also* ¶¶ 102-04. Relator's purely speculative "sequence" theory is the only manner in which Relator has alleged that Defendants *might possibly* have submitted false claims to the government in violation of the FCA. In other words, Relator speculates that false claims "must have been submitted," although he cannot say when, by whom, what payments they sought, or what they actually said that was false. Such conjecture fails *Iqbal's* plausibility standards, as it is equally plausible that false research data were not reported in a claim for payment.

Further, *none* of the grant application or progress report instructions to which Relator cites actually requires that a grantee include in a claim for payment (1) data from every experiment conducted during a year that was funded by a grant or (2) the same figures from publications that received funding from a grant. Indeed, those instructions merely require the grant application or progress report to include *in its bibliography section* a simple listing of the publications that support any references cited in a grant application or publications that resulted from a project in a progress report. Relator admits as much. *See, e.g.*, Dkt. 25, ¶ 102 ("In a grant application, the institution must provide a bibliography of any references cited") (citing HHS, PHS, Grant Application (PHS 398), Part I, § 5.5.5, "Bibliography and References Cited/Progress Report Publication List," p. 1-48; SF 424 (R&R); Application Guide for NIH and Other PHS Agencies, Part I, § 4.4 "Other Project Information Form," pp. 58, 63); ¶ 103 ("In a grant progress report, the grantee institution must provide complete references to the publications . . . that have

resulted from the project”) (citing HHS, PHS, Grant Application (PHS 398), Part I, § 5.5.5, “Bibliography and References Cited/Progress Report Publication List,” p. 1-48; SF 424 (R&R); Application Guide for NIH and Other PHS Agencies, Part I, § 5.5 “PHS 398 Research Plan Form,” p. 114); ¶ 104 (“For non-competing continuation progress reports, the grantee institution must report publications resulting directly from the grant.”) (citing HHS, PHS, Non-Competing Continuation Progress Report (PHS 2590), § 2.6(E) “Publications,” p. 16)); ¶ 105 (“In a final progress report, the grantee institution must include . . . a list of resulting publications.”) (citing HHS, PHS, Final Progress Report Instructions, § B “Instructions for All Final Progress Reports (exclusive of SBIR/STTR Phase II Final Progress Reports),” p. I)).

Because the bibliography requirements upon which Relator bases his allegations do not require the submission to the grant agency of the *data* underlying the listed publications – which is the sole manner in which Relator claims that false data generated by Potts-Kant were included in claims for payment to the government – Relator’s Amended Complaint fails to state a claim upon which relief may be granted as to the inclusion of false data or statements in a grant application or progress report and should be dismissed pursuant to Rule 12(b)(6).

Moreover, even if the instructions to which Relator cites actually did require the inclusion of such data in applications or progress reports, Relator has still not set forth a plausible theory of liability because he has not identified – *anywhere* in the Amended Complaint – a *single false claim* that Defendants submitted to the government. “[W]hen a defendant’s actions, as alleged and as reasonably inferred from the allegations, *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment.” *Nathan*, 707 F.3d at 457 (emphasis in original). In *Nathan*, the Fourth Circuit determined that without such plausible

allegations, “a relator not only fails to meet the particularity requirement of Rule 9(b), but also does not satisfy the general plausibility standard of *Iqbal*. *Id.* (citing *Clausen*, 290 F.3d at 1313).

For instance, in *United States ex rel. Jallali v. Sun Healthcare Grp.*, the court dismissed the relator’s complaint despite the detailed description of billing schemes involving the alleged use of back-dated files and inappropriately signed orders because the relator had failed to plead the specifics of any claims that were actually submitted to the government. *See* No. 12–61011, 2015 WL 10687577, at *5 (S.D. Fla. 2015), *aff’d by Jallali v. Sun Healthcare Grp.*, No. 15-14231, 2016 WL 3564248 (11th Cir. July 1, 2016). Even though the relator had provided patient and billing records as exhibits to her complaint, “all of her allegations concern[ed] charting and coding and [were] ***premised on the assumption*** that those charts and codes ultimately translated into particular bills for particular treatments on particular patients that were submitted to the government.” *Id.* at *6 (emphasis added). As a result, the court dismissed the relator’s complaint. *Id.* at *8.

Similarly, here, Relator has plead no plausible facts to support his assumption that the allegedly false data in a publication were also included in any grant application or progress report actually submitted to the federal government. Despite the many grants referenced in Exhibits C and C-1, Relator has not pointed to any grant application or progress report from one of those grants as actually containing false data or a false certification.⁷ Because the

⁷ With respect to his reverse false claims allegations in Count III specifically, the only allegation Relator makes is that Defendants “knowingly and improperly sought to avoid or decrease their obligations to pay money to the Government.” *See* Dkt. 25, ¶ 344. Such bare bones, conclusory pleading not only fails to state a claim under Rule 12(b)(6), but it also fails to meet the heightened pleading requirements of Rule 9(b) because Relator has failed to provide the particulars of even a ***single false claim*** that Defendants submitted to the government. *See Phipps v. Agape Counseling and Therapeutic Servs., Inc.*, No. 3:13–CV–166, 2015 WL 2452448, at *6 (E.D. Va. May 21, 2015) (dismissing the relator’s reverse false claims allegations against the Defendant because they only consisted of “boilerplate assertions that simply restate[d] the statutory language of § 3729(a)(1)(G)”; *see also United States ex rel. Rector v. Bon Secours Richmond Health Corp.*, No. 3:11–CV–38, 2014 WL 1493568, at *11 (E.D. Va. Apr. 14, 2014) (stating that “where false-claims counts and reverse-false-claims counts are two sides of the same coin, the same analysis applies to both”) (internal quotations omitted).

“submission of a specific claim [in an FCA case] is a critical element and not merely a ‘ministerial act’[.]” Relator has failed to plead a false claim or false certification in accordance with the standards set forth this Circuit. *See id.* (quoting *Clausen*, 290 F.3d at 1311).

2. The Amended Complaint Does Not Plead Plausible Facts Showing that Any Claim Was False and Must Be Dismissed Under Rule 12(b)(6).

Assuming *arguendo* that Relator had adequately alleged even a single false claim that Defendants had submitted to the government, Relator has not adequately pleaded falsity pursuant to Rule 12(b)(6). Relator’s only evidence of falsity consists of nothing other than literally true bibliography listings and differences in experimental outcomes, all of which have been rejected as indicators of falsity by the courts. As a result, Relator has not pleaded falsity, and his Amended Complaint should be dismissed under Rule 12(b)(6).

a. Accurate Citations to Publications Are Not False.

First, with respect to the instructions to which Relator cites that only actually require the inclusion of a ***bibliography*** listing publications in grant applications or progress reports, Relator has not alleged that Duke failed to meet those requirements. Moreover, even if Relator had made such an allegation, an accurate citation in a grant application or progress report to a publication is not a false statement as a matter of law, even if the publication itself contains allegedly false or fabricated data. *See United States ex rel. Milam v. The Regents of the Univ. of California*, 912 F. Supp. 868, 884 (D. Md. 1995) (“The Court finds, as a matter of law, that a correct citation cannot constitute a false claim[.]”). In *Milam*, the relator alleged that if data or statements in a publication were false, then every citation to that publication in a grant application or progress report would constitute a false statement for FCA liability. *Id.* at 882. In rejecting the relator’s argument, the Court noted:

[T]here is no dispute that the articles actually were published in the cited journals. Perhaps False Claims Act liability for mere citations could be imposed if the citations themselves were fabricated. However, in this case, Milam is attempting to bootstrap her substantive complaints about defendants' research into additional claims for citations.

Id. at 883. Because the FCA “only creates liability for false statements, not for accurate citations[,]” the court dismissed the relator’s argument and granted summary judgment for the defendants. *Id.* at 882.

Similar to *Milam*, Relator in this case cites to multiple grant instructions requiring Duke to include a bibliography listing publications cited within the text of the grant application or progress report or that were published during the funding period. Dkt. 25, ¶¶ 102-05. Not only does Relator not cite to any particular grant application or progress report that was submitted that included such references, Relator also has not alleged generally that any citations included in grant applications or progress reports were *themselves fabricated*. In fact, there is no dispute in this case that every publication to which Relator cites was, in fact, published, and Relator admits as much. *See, e.g.*, Dkt. 25, ¶ 164 (“This paper was published in January 2008 in the American Journal of Physiology.”); ¶¶ 169; 175; 181; 186; 192; 198; 204; 210; *see also* Ex. E, ¶¶ 4; 9; 15; 21; 26; 34; 39, 45; 50; 56; 62; 68; 73; 78; 83; 88; 93; 98; 103; 108; 114; 119; 124; 129; 134; 139. As a result, Relator cannot rely upon accurate citations to publications in grant applications or progress reports as the basis for his false claims, even if the publications included allegedly false data.

b. Conclusory Allegations of Differences of Scientific Opinions Cannot Form the Basis of FCA Liability.

In addition, Relator alleges that a large amount of the data contained in publication figures was false because researchers were unable to replicate experiments after the discovery of Potts-Kant’s alleged research misconduct. *See, e.g.*, Dkt. 25, ¶¶ 172-74 (“Another researcher

later tried to repeat the Foster Lab’s results but was unsuccessful and observed results that were contrary to published results.”); ¶¶ 189-91 (“Another researcher tried to re-run this experiment and observed results that were the opposite of the Foster Lab’s published results.”); ¶¶ 195-97 (“One Duke University researcher later found that the data in this publication was manipulated, and another was unable to repeat the Foster Lab’s reported results”); ¶¶ 201-03 (“A Duke University researcher re-ran the multiplex experiments and could not repeat the Foster Lab’s reported results.”). Again, though, Relator’s claims must fail because FCA liability cannot attach to “expressions of opinion, *scientific judgments* or statements as to conclusions which reasonable minds may differ cannot be false[.]” *See United States ex rel. Hill v. Univ. of Med. and Dentistry of New Jersey*, 448 F. App’x. 314, 316 (3d. Cir. 2011) (quoting citations omitted) (emphasis added).

In *Hill*, the relator had alleged that the defendant produced false data by not following proper scientific protocols because the results obtained by the defendant contradicted her own, and she was unable to replicate the data. *Id.* at 315. In affirming the district court’s grant of the defendants’ summary judgment motion, the court noted that not being able to replicate data could be “proof of a mistake” or indicative of negligence in performing the experiments, but it did not prove that the data were false. *Id.* at 317. Therefore, in this case, where Relator alleges that data were false because (1) researchers were unable to replicate the data or (2) the results from other researchers were different than Potts-Kant’s results in connection with publications that stated reported research was funded by NIH grants, Relator has not sufficiently alleged falsity, and his claims should be dismissed pursuant to Rule 12(b)(6). *See* Dkt. 25 ¶ 270.⁸

⁸ Relator references 22 specific grants under the category “Reviewers cannot repeat the Foster lab’s results” in paragraph 270 of his Amended Complaint: AI081672, AI58161, AI068822, AI089756, ES016126, ES11961, ES12717, ES16347, ES16659, 3S020426, ES12496, ES020350, HL05009, HL086887, HL91335, HL084917,

3. The Amended Complaint Does Not Plead Plausible Facts Showing that a False Claim Was Material and Must Be Dismissed Under Rule 12(b)(6).

Relator makes conclusory allegations and bare bones assertions with respect to the materiality element of his claims. *See id.* ¶ 342 (making the conclusory statement that “[t]he previously identified false statements and records made and used by Defendants were material, because they had a natural tendency to influence, or be capable of influencing, the NIH’s and EPA’s payment of grant funds”). Under the FCA, “the term ‘material’ means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4). In the Supreme Court’s recent decision in *Univ. Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), the Court stated that the FCA’s materiality requirement is “rigorous” and “demanding” and specifically rejected the argument that “materiality is too fact intensive for courts to dismiss [FCA] cases on a motion to dismiss[.]” *Id.* at 2002–04 & n.6. Therefore, to survive a motion to dismiss, “[FCA] plaintiffs must . . . plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by . . . pleading facts to support allegations of materiality.” *Id.* at 2004 n. 6; *see also Knudsen v. Sprint Communc’n Co.*, No. C13-04476 CRB, 2016 WL 4548924, at *13 (N.D. Cal. Sept. 1, 2016) (post-*Escobar*, rejecting the government’s claim that the standard for pleading materiality is an “easy” one) (internal quotations omitted).

Under the Supreme Court’s “rigorous” and “demanding” materiality standard, a relator must do more than merely allege that the government would not have paid a defendant’s claims if it had known of a failure to meet a requirement. *Escobar*, 136 S. Ct. at 2002-03. A material misrepresentation is one to which the government “would attach importance” in deciding

HL068072, HL058795, HL084123, HL079915, HL081285, HL7729, HL91335, and P50-HL084917. *See* Dkt. 25, ¶ 270.

whether to pay and where knowledge of the misrepresentation “would have induced [the government] to act differently.” *Id.* at 2003, n.5. The Supreme Court stated one way a relator could establish materiality would be by showing that “the government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.” *Id.* at 2003. Additionally, the Supreme Court determined that evidence that the government “expressly identif[ied] a provision as a condition of payment” was “relevant” but “not automatically dispositive.” *Id.* Thus, under *Escobar*, the issue is not whether the government *could* decline to pay if it knew of the defendant’s misrepresentation, it is whether the government *would* decline to pay.

The Amended Complaint does not allege plausible facts that the government *routinely withholds payment* for failing to comply with *any* of the numerous federal regulations and grant policy statements cited by Relator underlying the two alleged certifications. Indeed, Relator’s sole allegations in support of the materiality of his false certifications claims are conclusory statements that Duke’s certifications were material to the government’s decision to fund the grants identified in Exhibit C, Exhibit, C-1, and other unspecified grants awarded between 2007 and 2015. *See* Dkt. 25 ¶¶ 342; 365; 389; 399; 400. Relator does not even make an unsubstantiated allegation that the Government would have actually refused payment had it known that Duke falsely certified compliance with any of the regulations or policy statements underlying the alleged certifications. At best, Relator’s boilerplate allegations merely imply that the government had the *option* to decline payment for the types of regulatory and policy violations alleged by Relator. This is insufficient under *Escobar*. *See, e.g., United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447-48 (7th Cir. 2016) (“*Sanford-Brown, Ltd. II*”) (affirming dismissal on summary judgment post-*Escobar* on the basis that “the most [relator] has

shown is that [the defendant's] supposed noncompliance and misrepresentations would have entitled the government to decline payment") (citing *Escobar*, 136 S.Ct. at 2004).⁹

Moreover, Relator's own allegations support that, rather than automatically withholding payment, the government addresses noncompliance with the cited regulations, grant policies, and assurance requirements through a variety of alternative regulatory enforcement mechanisms. *See* Dkt. 25, ¶ 107 (alleging that, for the grant application or progress report certifications, "[i]f a grant is awarded on the basis of false or misrepresented information, or if a grantee does not comply with [the] public policy requirements [underlying the grant application or progress report certifications], NIH may take any necessary and appropriate action, including using any of the remedies described in Administrative Requirements—Enforcement Actions or other available legal remedies") (emphasis in original); ¶ 112 (alleging that, for the institutional assurances, "HHS may bring an enforcement action that results in debarment, suspension or any other appropriate action"). Because Relator fails to plead materiality in accordance with the Supreme Court's guidance in *Escobar*, his false certification claims must also be dismissed.

In addition, the remainder of the allegations in the Amended Complaint concerning materiality are mere recitations of the standard or completely speculative, and thus insufficient under *Twombly* and *Iqbal*. *See* Dkt. 25, ¶ 150 ("It is unlikely that the NIH would award any significant grant funding for pulmonology research that does not include preliminary studies based on *flexiVent* and/or multiplex experiments."); ¶ 355 (Count I) ("The false or fraudulent

⁹ *See also United States v. Fulton Cnty., Georgia*, No. 1:14-CV-4071-WSD, 2016 WL 4158392, at *8 (N.D. Ga. Aug. 5, 2016) (allegations that failure to meet certain requirements were "conditions of the contract" insufficient under *Escobar* where relators failed to allege that "Defendants misrepresented matters 'so central' to the Contract that the government 'would not have paid [Defendants'] claims had it known of these violations'") (internal citations omitted); *United States v. N. Adult Daily Health Care Ctr.*, No. 13-CV-4933 (MKB), 2016 WL 4703653, at *12 (E.D.N.Y. Sept. 7, 2016) ("Because Relators have not alleged that noncompliance with Title VI and the DOH regulations listed in the Amended Complaint would have influenced the government's decision to reimburse [defendants], Relators have not stated a claim under an implied false certification theory of liability[.]").

statements of research results, publications that include false, fabricated, and/or fraudulent statements of research results, and false certifications were material to the grant-making agencies' decision to fund the grants."); ¶ 365 (Count II) ("The false records or statements were material to the grant-making agencies' decision to fund the grants."); ¶ 376 (Count III) ("Defendants have knowingly made or used false and statements material to Duke University's obligation to repay grant funds."); ¶ 389 (Count IV) ("The false or fraudulent certifications were material to the NIH's decision to fund each grant paid to Duke University during some or all of the calendar years from 2007 to 2015."); ¶ 399 (Count V) ("The false certifications in Duke University's Institutional Assurance and Annual Reports were material."). Such bare assertions of materiality are not enough to meet the "rigorous" and "demanding" standard embraced by the Supreme Court in *Escobar*; as a result, Relator's Amended Complaint should be dismissed for failure to allege materiality pursuant to Rule 12(b)(6).

4. The Amended Complaint Does Not Plead Plausible Facts Showing that Defendants Acted with the Required Scienter and Must Be Dismissed Under Rule 12(b)(6).

Relator's Amended Complaint also fails to adequately plead knowledge under the FCA, which defines "knowingly" to include (1) actual knowledge of the information; (2) deliberate ignorance of the truth or falsity of the information; or (3) reckless disregard of the truth or falsity of the information. *See* 31 U.S.C. §3729(b). Although a relator may plead knowledge under the FCA generally, the relator must still plead specific facts supporting an inference that Defendants knowingly submitted claims for payment. *See Iqbal*, 556 U.S. at 686-87 ("It is true that Rule 9(b) requires particularity when pleading 'fraud or mistake,' while allowing '[m]alice, intent, knowledge, and other conditions of a person's mind [to] be alleged generally.'") (citations omitted). "Rule 9 merely excuses a party from pleading [states of mind] under an *elevated*

pleading standard. It does not give him license to evade the less rigid though still operative strictures of Rule 8.” *Id.* at 686-87.

Relator spends more than six pages attempting to demonstrate that Duke had the requisite scienter for an FCA claim; however, the Amended Complaint does not contain any facts showing that Duke had **knowledge** that grant applications or progress reports included allegedly false research results or allegedly false certifications. Instead, what Relator has pleaded are allegations that Duke had **knowledge** of Potts-Kant’s allegedly fraudulent **research**. *See e.g.*, Dkt. 25, ¶ 280 (“Senior managers at Duke University . . . had actual and specific knowledge of **research misconduct** . . .”); ¶ 325 (“Duke University had actual knowledge of **research misconduct** by Potts-Kant in March 2013”); ¶ 316-17 (alleging that Potts-Kant, Foster, Duke, and DUHS knew that the “**research results**” were false or fraudulent) (emphasis added). Even where Relator mentions multiple ways in which Duke and DUHS had knowledge of the alleged falsity of Potts-Kant’s research results, *see id.* ¶¶ 339-41, Relator has not pleaded that Potts-Kant, or any other Defendant, knew that certain false research results or false certifications were included in specific grant applications or progress reports submitted to the government. As a result, none of Relator’s allegations regarding knowledge supports an inference that Duke knowingly submitted false claims for payment, and Relator has not met the pleading requirements for this element set forth in the Federal Rules.

5. Counts IV and V Certification Claims Fail to Plead a Viable FCA False Certification Theory of Liability Under *Escobar*.

In Counts IV and V, Relator asserts false certification claims by alleging that: (1) Duke submitted false claims that were not compliant with annual institutional assurances submitted to ORI (“institutional assurances”); and (2) Duke falsely certified compliance with certification statements in grant applications and progress reports submitted to NIH and EPA (“grant

document certifications”). To the extent that Relator relies on an implied false certification theory of liability, Relator has not pleaded the two conditions necessary to survive a motion to dismiss under *Escobar*. In *Escobar*, the Supreme Court held that a relator may rely on an implied certification theory where two conditions are met: (1) the defendant submitted a claim that “makes a specific representation about the goods or services provided;” and (2) that “the defendant’s failure to disclose noncompliance with the material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.” *Escobar*, 136 S. Ct. at 2001. If both conditions are met, the relator must **further** meet the materiality element by showing that the failure to disclose noncompliance with certain requirements was material to the government’s payment decision. *Id.* at 2002. As discussed below, Relator fails to meet both of *Escobar*’s conditions. Further, as discussed above, *see* Section IV.A.3 *surpa*, Relator also fails to establish *Escobar*’s materiality element. Consequently, Relator’s certification theory must be dismissed.

In *Escobar*, the relator alleged that the defendant had submitted claims for payment that communicated **specific** information to the government, including treatment codes identifying the specific treatments provided, as well as information about the specific providers dispensing the treatment. *Id.* at 1997. As the Supreme Court described:

[B]y submitting claims for payment using payment codes that corresponded to specific counseling services, Universal Health represented that it had provided individual therapy, family therapy, preventive medication counseling, and other types of treatment. Moreover, Arbour staff members allegedly made further representations in submitting Medicaid reimbursement claims by using National Provider Identification numbers corresponding to specific job titles. ***And these representations were clearly misleading in context.***

Id. at 2000 (emphasis added).

Applying the two conditions of *Escobar*, the Seventh Circuit recently affirmed its prior rejection of an implied certification claim against Sanford-Brown College. *Sanford-Brown, Ltd.*

II, 840 F.3d at 447. In *United States v. Sanford-Brown, Ltd.*, 788 F.3d 696 (7th Cir. 2015) (“*Sanford-Brown I*”), *abrogated by Escobar*, 136 S. Ct. 1989, *reinstated in part, superseded in part sub nom* 840 F.3d 445 (7th Cir. 2016), the relator alleged that Sanford-Brown College violated the FCA by accepting subsidies under Title IV of the Higher Education Act while failing to comply with certain regulatory requirements promulgated by the Act. In particular, the relator alleged that the College had entered into a Program Participation Agreement (PPA) with the federal government which contained language requiring the College to certify its compliance with Title IV’s regulations. *Sanford-Brown I*, 788 F.3d at 705. The relator claimed that, because the College’s practices in actuality violated Title IV, its representations in the PPA, and its Title IV subsidy claims, by implication, were false. *Id.* at 708.

Revisiting its decision in light of *Escobar*, the Seventh Circuit held that the relator had failed to establish that the College “made any representations at all in connection with its claims for payment, much less false or misleading representations,” and thus neither condition of *Escobar* was satisfied to support the relator’s implied certification claim. *Sanford-Brown, Ltd. II*, 840 F.3d at 447.

Like the relator in *Sanford-Brown*, here, Relator has not alleged that any of the purported grants submitted by Duke contained a single specific representation, and thus, he has not sufficiently pleaded the first condition of *Escobar*. Absent any allegations in support of the first condition, Relator cannot establish how the specific representations (which are not alleged) are directly false or “misleading half-truths.” *See, e.g., Sanford-Brown, Ltd. II*, 840 F.3d at 447 (affirming dismissal on summary judgment because the relator failed to establish that the defendant “made any representations at all in connection with its claims for payment, much less false or misleading representations”). Because neither *Escobar* condition is satisfied in this case,

Relator cannot state a claim under an implied certification theory, and therefore, Relator's impliedly false certification claims – if they exist at all – should be dismissed pursuant to Rule 12(b)(6).

Relator's express certification allegations, *see* Dkt. 25, ¶¶ 91, 92, 99, 100, fail for the same reasons his direct false claims theory fails. *See* Section IV.A.1, *supra*. That is, Relator has not alleged even one grant application or progress report that contained the alleged false express certifications, Relator has not adequately pleaded falsity, and Relator has not pleaded materiality in accordance with the requirements set forth in *Escobar*. As a result, Relator's express false certification claims must also fail pursuant to Rule 12(b)(6).

B. Relator Also Has Failed to Plead Fraud with the Particularity Required by Rule 9(b).

1. Relator Failed to Plead the Particulars of a False Claim.

Not only has Relator failed to allege even a *single false claim*, he has also failed to plead the particulars of any claims, including *what* falsity was included in the claim or *when* it was submitted. As stated previously, it is not enough in the Fourth Circuit to merely allege the details of a fraudulent scheme without particularly pleading that the defendant presented a false claim to the government. *See Nathan*, 707 F.3d at 456-57. Therefore, for a relator to survive a motion to dismiss for failure to plead fraud with particularity, he must provide facts to support a link between the allegedly false or fraudulent conduct and a claim for payment that has *actually* been submitted to the government.¹⁰ *United States v. Kernan Hosp.*, 880 F.Supp. 2d 676, 683 (D. Md. 2012).

¹⁰ While the Fourth Circuit has not expressly addressed the question of whether representative claims must be actually identified in a relator's complaint to meet the 9(b) pleading standard, the Eastern District of Virginia has concluded that "[the] ruling in *United States ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc.*, 707 F.3d 451 (4th Cir. 2013), suggests that it follows [other] circuits requiring identification of at least one representative claim." *See Hunter Labs.*, 2014 WL 1928211, at *7 (citing favorably to *Clausen*, 290 F.3d at 1312 (holding that the relator's detailed descriptions of alleged schemes by the defendant to increase laboratory revenues

In *Kernan Hospital*, the relator alleged that the defendant devised a scheme to fraudulently code a secondary diagnosis to increase reimbursement from federal healthcare programs, in violation of the FCA. *Id.* at 678. The relator’s complaint provided significant details about this scheme, which included allegations that coding specialists specifically reviewed every chart for evidence justifying the secondary diagnosis and used sticky notes to identify such charts, that the physicians removed the sticky notes after agreeing with the recommendations, and that the coders were instructed to select a specific diagnosis without any independent analysis being conducted. *Id.* at 679.

When asked *what* the specific false claims at issue were during a hearing, the relator’s counsel identified the hospital cost reports submitted to the state. *Id.* at 686-87. In concluding that the relator had not met the particularity requirements of Rule 9(b), the court stated that the complaint merely alleged a “complicated scheme” to increase government reimbursement but was “silent as to the next step or link in the [FCA] liability mechanism – namely, that these fraudulent diagnoses made their way to cost reports submitted to the [state] and actually caused the [state] to pay Kernan for services not rendered.” *Id.*

Like the relator in *Kernan Hospital*, in this matter, Relator has alleged that Defendants “have engaged in systemic research misconduct and fraud, and failed to comply with the terms, conditions, and assurances of their grant awards.” Dkt. 25, ¶ 3. However, he has failed to allege even one specific claim for payment that was actually submitted to the Government. As discussed above in Section II.C, *supra*, the crux of the allegations in Relator’s Amended Complaint is that Duke submitted false claims for payment to the Government because

did not “provide any factual basis for his conclusory statement tacked on to each allegation that bills were submitted to the government as a result of these schemes”) and *United States ex rel. Joshi v. St. Luke’s Hosp., Inc.*, 441 F.3d 552, 557 (8th Cir. 2006) (finding that the relator’s FCA complaint did not satisfy Rule 9(b)’s particularity requirement because it did not provide even a “single, specific instance of fraud” that “specif[ied] the time, place, and content of their acts and the identity of the actors”)).

publications that included allegedly false data were allegedly required to be reported in grant progress reports. *See, e.g.*, Dkt. 25, ¶¶ 218-19. Relator pleads this same general scheme, asserting legal conclusions that claims ***must have been submitted***, over and over again.¹¹ *See id.* ¶¶ 159-219; Ex. E. What Relator has done is precisely what the Fourth Circuit in *Nathan* warned against – he has “describe[d] a private scheme in detail but then [] allege[d] simply and without any stated reason . . . that claims requesting illegal payments ***must have*** been submitted, ***were likely*** submitted or ***should have*** been submitted to the Government.” *Nathan*, 707 F.3d at 457 (internal quotations omitted) (emphasis added); *see also United States. ex rel. Jones v. Collegiate Funding Servs., Inc.*, No. 3:07CV290-HEH, 2011 WL 129842, at *19 (E.D. Va. Jan. 12, 2011) (“*Jones I*”), *aff’d*, 469 F. App’x 244 (4th Cir. 2012) (“*Jones II*”) (“[T]he simple fact that Defendants ***could*** submit such claims to the [government] does not permit the inference that Defendants ***did*** submit any such claims. Because Relators do not provide any facts from which the Court could infer the actual submission of claims, the Court certainly cannot reasonably extrapolate that Defendants submitted any ***false*** claims.”) (emphasis in original).¹² By not providing the specifics of ***who*** submitted the false claim, ***what*** specific grant application or

¹¹ The closest Relator comes to pleading an ***actual*** claim for payment is his mention of the June 2013 Progress Report for grant P01AI081672. *See* Dkt. 25, ¶¶ 288-96. However, Relator’s attempt to use this grant progress report as a representative example of a claim for payment fails because he has not alleged ***who*** submitted the false data in the Progress Report, ***what*** the false data consisted of, ***where*** the false data were contained in the Progress Report, or ***how*** the data were false. Without pleading these specifics, Relator has not successfully pleaded a representative example of a false claim.

¹² In *Jones I*, the Eastern District of Virginia found it insufficient for Relators “to support their contention that Defendants submitted any claims to the DOE [using] their assertion that they have personal knowledge false certifications were indeed used to get legally false claims paid.” 2011 WL 129842, at *19 (internal quotations omitted). According to the District Court, “Relators’ purported ‘personal knowledge’ amounts to nothing more than a naked assertion . . . [because they] have not presented any facts supporting this contention.” *Id.* On appeal, the Fourth Circuit affirmed dismissal of relator’s complaint where the relator “had no personal knowledge of any particular claims submitted,” and failed to allege specifics of any claim, such as “payments, dates, or other indicia from which a specific claim can be inferred to have been submitted.” *See Jones II*, 469 F. App’x at 250. Here, the glaring absence of any specifics at all makes it evident that Relator has no personal knowledge, and Relator’s Amended Complaint should be similarly dismissed.

progress report contained the false claim, *when* the false claim was submitted, or *how* the claim was false, Relator has failed to meet the particularity requirements of Rule 9(b), and his Amended Complaint should be dismissed as a result.

2. Relator’s False Certification Claims Also Are Too General to Meet Rule 9(b)’s Heightened Pleading Requirements.

Similarly, with respect to Relator’s false certification theories of liability, Relator has not connected Duke’s allegedly false certifications to any *specific* federal payments of grant funds and has not pleaded the “who, what when, where, and how” of the alleged false certifications.¹³ *See Hunter Labs.*, 2014 WL 1928211, at *7; *Kellogg, Brown & Root*, 525 F.3d at 379. Instead, Relator has merely provided a detailed description of the federal regulations and grant policy statements that govern recipients of federal grant funding. But it is the false claim itself – not the federal regulations – that Relator must plead with particularity. *See Hunter Labs.*, 2014 WL 1928211, at *6 (stating that because FCA liability arises from the “submission of a fraudulent claim to the government, not the disregard of government regulations, . . . it is the false claims which must be alleged with particularity”) (internal quotations and citations omitted).

At best, Relator’s allegations identify the *what* – that is, the institutional assurances submitted to ORI and the grant application and progress report certifications submitted to the NIH and EPA. Absent from Relator’s Amended Complaint, however, are any allegations (conclusory or otherwise) that identify *who* submitted these certifications, *when* they were

¹³ The only allegations Relator makes related to his false certification claims are broad, conclusory statements that not only fail to allege *even one claim containing a false certification* but also fail to provide the specifics required by Rule 9(b). *See, e.g.*, Dkt. 25 ¶ 382 (“Duke University falsely certified its compliance with its assurances to the Government respect to the Regulations *for some or all* of the calendar years from 2007 to 2015”) (emphasis added); ¶ 395 (“The false records or statements include the false certifications in Duke University’s Institutional Assurance and Annual Reports, submitted to ORI with respect to *some or all* of the calendar years from 2007 to 2015”) (emphasis added); ¶ 396 (“The false records or statements also include the false certifications in all Duke University’s grant applications and grant progress reports for all NIH grants submitted *after the date on which Duke University knowingly failed to comply* with its assurances to the Government with respect to the Regulations.”) (emphasis added).

submitted, or *how* they were false. *See, e.g., Fulton Cnty.*, 2016 WL 4158392, at *7 (dismissing the complaint under Rule 9(b) because complaint “[did] not elaborate on the content of the payroll certifications, the dates they were submitted or due, or who prepared and submitted them).

Most importantly, and similar to his allegations regarding the inclusion of false data in grant applications or progress reports, Relator has not pleaded a link between the allegedly wrongful conduct and a claim for payment that was *actually* submitted to the Government. *See Kernan Hosp.*, 880 F. Supp. 2d at 683 (dismissing the relator’s FCA complaint for failing to link allegedly fraudulent diagnoses to cost report claims submitted to the state). “[S]tanding alone, allegations of violations of federal regulations or laws are insufficient if a plaintiff cannot identify with particularity any *actual* false claims submitted by defendant to the government.” *United States ex rel. Grant v. United Airlines, Inc.*, No. 2:15-CV-00794-DCN, 2016 WL 6823321, at *4 (D.S.C. Nov. 18, 2016) (internal citations and quotations omitted) (emphasis added). Because Relator has pleaded neither the “who, what, when, where, and how” of the false certifications, nor any specific claims that were submitted that included the false certifications, Relator’s false certification claims must fail under Rule 9(b) as well.

3. Relator Has Not Pleaded with Particularity How the Data Included in Grant Applications or Progress Reports Were False.

In addition to not having pleaded the particulars of representative claims that were submitted to the Government, Relator has not properly met the Rule 9(b) pleading standard for falsity. A relator must plead a “false statement or fraudulent course of conduct” to survive a motion to dismiss. *Skinner v. Armet Armored Vehicles, Inc.*, No. 4:12-CV-00045, 2014 WL 4243670, at *9 (W.D. Va. Aug. 26, 2014) (“An FCA claim requires, at the most basic level, a false statement or fraudulent course of conduct.”) (internal quotations omitted). To satisfy the

falsity element, “the statement or conduct alleged must represent an objective falsehood.” *Kellogg Brown & Root*, 525 F.3d at 376; *see also Skinner*, 2014 WL 4243670, at *7. As the Fourth Circuit has explained, “fraud may only be found in expressions of fact which (1) admit[] of being adjudged true or false in a way that (2) admit[] of empirical verification.” *Harrison*, 176 F.3d at 792 (internal quotations omitted) (alteration in original). In other words, to establish the falsity element at the pleading stage in the Fourth Circuit, a relator must allege specific false statements or fraudulent conduct, which, *if true*, would constitute objective falsehoods.

Relator speculates that data from the publications – which are not themselves claims for payment – are false or fraudulent because (1) Potts-Kant obtained results from the *flexiVent* machine that were inconsistent with the APTI machine, which was used before the *flexiVent* technology had been developed; (2) Potts-Kant made up the data; (3) Potts-Kant altered the data results after running the experiments; and (4) researchers were unable to replicate experiments after the discovery of Potts-Kant’s alleged research misconduct. *See* Dkt. 25 ¶¶ 4, 152, 155-58. Relator fails, however, to plead any *specific* false data that were included in any *specific* grant application or progress report actually submitted to the government, and instead relies on the generalized conclusion that Potts-Kant “committed research misconduct and fraud on nearly every experiment or project with which she was involved.” *Id.* ¶ 154; *see also id.* ¶¶ 162-165; 166-170; 171-176; 177-182; 183-187; 188-193; 194-199; 200-205; 206-211; 213; 220; *see also* Ex. E, ¶¶ 1-5; 6-10; 11-16; 17-22; 23-27; 28-30; 31-35; 36-40; 41-46; 47-51; 52-58; 59-63; 64-69; 70-74; 75-79; 80-84; 85-89; 90-94; 95-99; 100-04; 105-09; 110-15; 116-20; 121-25; 126-30; 131-35; 136-40 (generally alleging in each of these paragraphs that: “Potts-Kant and Foster co-authored a scientific paper,” “Potts-Kant claimed to perform experiments . . . data supposedly

produced by these experiments are contained in [figures] of the paper,” “Potts-Kant falsified and/or fabricated the data,” and the “scientific paper, premised upon fraudulent research, cites financial support from [NIH or EPA grant number]” or some similar version of those statements). This is insufficient under Rule 9(b).¹⁴

For example, although Relator alleges that Potts-Kant performed the experiments that produced data used in Figures 1C, 2C, 4C, and 5C in the publication *Hyaluronan Fragments Contribute to the Ozone Primed Immune Response to Lipopolysaccharide* and then concludes that “Potts-Kant falsified and/or fabricated the data in the paper[,]” he fails to specify **how** the particular data in the figures were false and **when** the experiments were performed that contributed to the figures. *Id.* ¶¶ 172-73. In addition, Relator fails to make any allegations regarding **what** experiments had no raw data, could not be repeated, or contained manipulated results. By not providing the specifics of **how** the data included in the publications – which are **not claims** for payment themselves – were false, Relator’s Amended Complaint fails to meet Rule 9(b)’s heightened pleading threshold.

Relator evidently acknowledges that the allegations discussed above are insufficient to plead falsity under Rule 9(b) because the Amended Complaint includes a section detailing how Dr. Ledford identified “**specific** ‘manipulated’ data.” *See id.*, Section (G)(vi) (emphasis added); Ex. D. Once again, though, Relator’s attempt to cure his pleading deficiencies by identifying a specific instance of falsity is likewise deficient. Despite the detailed description of how the data

¹⁴ In support of these speculative assumptions, Relator relies upon anecdotal “facts” he claims to have learned from “discussions” he had with Pulmonary Division personnel who were involved with a “review of the Foster Lab data” after EPK was terminated. *See* Dkt. 25 ¶¶ 229, 230, 233. Although Relator claims to have participated in this review effort, *see id.* ¶ 232, he is unable to provide any information supporting his legal conclusions of falsity beyond unsubstantiated and conclusory hearsay from PIs and other researchers. *See id.*, e.g., ¶ 241 (“Dr. Que reached this conclusion. So, too, did Dr. Ledford, who observed that data reported for Dr. Hollingsworth’s epigenetic work involving maternal diesel exposure was entirely made up.”). Most importantly, Relator filed this lawsuit approximately six weeks after Potts-Kant’s termination, before the PIs’ investigation and review of data had even been completed. Therefore, his reliance upon initial unconfirmed anecdotal statements is not only premature, but it also lacks the specificity required by Rule 9(b).

contained in Exhibit D demonstrated discrepancies between the machine raw data and data produced by Potts-Kant, nowhere in this section does Relator link this false data with the submission of a claim for payment. *See id.* ¶¶ 271-78. Without identifying the specifics of any claim that included the allegedly false data Relator describes in ¶¶ 271-78, Relator has not met the heightened pleading requirements of Rule 9(b), and his Amended Complaint must be dismissed.

C. **Relator Has Failed to Meet the Pleading Standards of Rules 12(b)(6) and 9(b) for Any Claim Against DUHS.**

Notably, throughout the 542 paragraphs contained in Relator's Amended Complaint and supplemental Exhibit E, Relator does not allege that *one single claim* for payment that allegedly contained false or fabricated data or a false certification was submitted by or paid to **DUHS**. *See* Dkt. 25, ¶¶ 222-26; *see also* Ex. C (titled "Grants *to Duke University* Based on False Data from 2006-2014) (emphasis added) and Ex. C-1 (titled "Grants *to Other Institutions* Obtained with False Foster Lab Data") (emphasis added); Dkt. 25, Count IV ¶¶ 380-91 (stating in the title that the count applies to both Duke and DUHS but then only making allegations against "Duke University" with respect to allegedly false certifications); ¶¶ 390, 401 (alleging that false certifications caused damages "in the amount of the federal funds paid to **Duke University** for all NIH grants during some or all the calendar years 2007 through 2015"). Absent any allegations that DUHS was involved in the submission of the alleged false claims based on any theory of liability, none of the factual allegations in Relator's Amended Complaint, even if true, supports a reasonable inference that DUHS knowingly submitted materially false claims to the government.

Failure to plead plausible facts about the submission of actual false claims or certifications under either §3729(a)(1)(A) or §3729(a)(1)(B) is grounds for dismissal. Because Relator has also failed to allege the existence of any government funds purportedly received by

DUHS to which it was not entitled to receive, Relator also fails to plead a plausible reverse FCA claim. As a result, Relator's Amended Complaint fails to state a claim against DUHS under Rule 12(b) and must be dismissed.

Moreover, Relator's claims against DUHS also fail under the heightened particularity standard of Rule 9(b) because in cases involving multiple defendants, Rule 9(b) requires that the complaint specify *each defendant's* alleged misconduct. See *Ahumada*, 2013 WL 2322836, at *3 (dismissing a complaint that failed to "plead any detailed allegations against [one of the defendants]" resulting in a failure to meet the "who, what, when, where, how" requirement of Rule 9(b)).

Defendants cannot simply "be grouped together without specification of which defendant committed which wrong." . . . "[W]hen a relator raises allegations of fraud against multiple defendants, the complaint must apprise each defendant of the specific nature of his or her participation in the fraud."

Id. at *3 (internal citations omitted); see also *United States ex rel. Brooks v. Lockheed Martin Corp.*, No. L-00-1088, 2005 WL 841997, at *2 (D. Md. Mar. 22, 2005) (dismissing the relator's complaint for "lump[ing] all of the Defendants together without identifying the person, or the corporation, making the alleged misrepresentations" or identifying "which Defendant(s) invoiced the government"); *Apple v. Prudential-Bache Sec., Inc.*, 820 F. Supp. 984, 987 (W.D.N.C. 1992) (dismissing a relator's complaint for pleading "common allegations to imply that each defendant is responsible for the statements and actions of the others"), *aff'd*, 993 F.2d 228 (4th Cir. 1993). Without providing specific allegations against *each defendant* named in a complaint, it is impossible for the defendants to determine "which of the misrepresentations they are specifically responsible for or what role they have played in the fraud." *Brooks*, 2005 WL 841997, at *2.

Here, Relator fails to allege specific claims against DUHS and, instead, inappropriately groups DUHS's conduct together with that of the other Defendants, most frequently Duke

University. In fact, *four out of the five counts* fail to specifically mention any factual allegations concerning DUHS at all. *See* Count I, ¶¶ 346-59 (stating in the title that the count is against “all defendants” but then only naming “Duke University” as the Defendant who allegedly submitted false claims to the Government); *see also* Count II, ¶¶ 360-69 (making allegations against “all defendants” but not specifically identifying DUHS’s actions); Count III, ¶¶ 370-79 (alleging in the title the count generally applies against “all defendants” but then stating that only “Duke University” has an obligation to repay grant funds); Count IV ¶¶ 380-91 (stating in the title that the count applies to both Duke and DUHS but then only making allegations against “Duke University” with respect to allegedly false certifications). As such, Counts I, II, III, and IV should be dismissed against DUHS. *See United States ex rel. Bender v. N. Am. Telecomms., Inc.*, 686 F. Supp. 2d 46, 50 (D.D.C. 2010) (dismissing four out of five claims against one of multiple defendants where the complaint failed to specifically mention any factual allegations in those counts against the one dismissed defendant).

Even where Relator specifically names DUHS in Count V, his allegations fail to differentiate between DUHS’s conduct and Duke’s conduct. *See* Dkt. 25, ¶ 394 (stating that “Duke University *and/or* DUHS knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims for grant payments, that were made in applications and progress reports submitted to the NIH.”) (emphasis added). Moreover, despite naming DUHS in Count V, *see id.* ¶¶ 393-94, it is unclear *which* Defendant Relator is alleging submitted false statements with respect to Duke’s assurance status and grant certifications because all of the subsequent allegations apply only to Duke. *See id. e.g.*, ¶ 395 (“The false records or statements include the false certifications in *Duke University’s* Institutional Assurance and Annual Reports”); ¶ 396 (“The false records or statements also include the false

certifications in all *Duke University's* grant applications and grant progress reports"); *see also* ¶¶ 397-401. Therefore, DUHS's role in the alleged fraud is ambiguous, not clearly stated, and tenuous at best. Because Relator has failed to plead any detailed fraud allegations against DUHS that would be sufficient to apprise DUHS of the allegations against it, Relator's Amended Complaint should be dismissed pursuant to Rule 9(b) with respect to DUHS.

D. The Amended Complaint Should Be Dismissed with Prejudice.

Relator already has had two full opportunities to plead his claim, yet has failed to state a claim for relief. Relator is not in possession of additional facts that will cure the substantive deficiencies in his pleading, and accordingly he should not be afforded leave to amend his complaint for a third time. *See Nathan*, 707 F.3d at 461 (district court may deny leave to amend where, *inter alia*, "the amendment would have been futile").

Relator claims to have had "direct and independent knowledge" of the facts underlying his claims for relief since the time he filed the Original Complaint more than three years ago, in May 2013. *See* Dkt. 1, ¶ 17 ("By virtue of his position and background, Relator Thomas became aware of research fraud within the Pulmonary Division at Duke University Medical Center and gained direct and independent knowledge of the allegations contained in this Complaint."); *see also* Dkt. 25, ¶ 15 ("Thomas has direct and independent knowledge of the information upon which the allegations are based"). Nearly all of the conduct in the Amended Complaint is alleged to have occurred well in the past, from 2006 to 2013. Thus, all of the facts underlying the alleged fraudulent conduct were available to Relator at the time he filed his Original Complaint in May 2013 and the Amended Complaint in November 2015. If Relator truly had

“direct and independent knowledge” of the “who, what, when, where, and how of the alleged fraud,” *Kellogg, Brown & Root*, 525 F.3d at 379, he would have pleaded those facts already.¹⁵

Furthermore, Relator already has had one attempt his “clarify the factual allegations and claims,” *see* Dkt. 23 (“Relator’s Motion for Leave to Amend”) at 2, but his amendments did nothing to “nudge[] [his] claims across the line from conceivable to plausible,” *Twombly*, 550 U.S. 544 at 570, let alone met Rule 9(b)’s heightened pleading standard. Relator cannot plead generalized allegations of wrongdoing and use discovery as a “fishing expedition” to establish his claims after the fact. *See Harrison*, 176 F.3d at 789. That is exactly what Rule 9(b) seeks to prevent. *See id.* (“The clear intent of Rule 9(b) is to eliminate fraud actions in which all the facts are learned through discovery after the complaint is filed”) (internal quotations omitted). Because Relator is not in possession of additional facts that will cure the substantive deficiencies in his pleading, he should not be afforded leave to amend his complaint for a third time.

V. CONCLUSION

For the reasons set forth above, Defendants Duke University and DUHS respectfully request that the Court grant their Motion to Dismiss Relator’s Amended Complaint for failure to state a claim pursuant to Rule 12(b)(6) and failure to plead fraud with particularity pursuant to Rule 9(b).

¹⁵ With respect to DUHS specifically, a review of Relator’s Amended Complaint makes clear that Relator is uncertain about what, if any, role DUHS had in the alleged fraud. *See e.g.*, Dkt. 25, ¶ 22 (pleading inconsistently that “Defendant Potts-Kant was an employee of *Duke University and/or DUHS* . . . Potts-Kant was approximately 25 years old when she began working for *Duke University*”).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 6, 2017 this document was filed electronically with the Clerk of the Court using the CM/ECF system, which will send a Notice of Electronic Filing to counsel of record in this matter in accordance with Federal Rule of Civil Procedure 5 and Local Rule of Civil Procedure 7(g), and by U.S. Mail upon the following party:

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